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**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA**

NEUROGRAFIX, a California corporation;
WASHINGTON RESEARCH
FOUNDATION, a not-for-profit Washington
corporation,

Plaintiffs,

vs.

SIEMENS MEDICAL SOLUTIONS USA,
INC., a Delaware corporation; and
SIEMENS AKTIENGESELLSCHAFT, a
German corporation,

Defendants.

CASE NO. CV 10-1990 MRP(RZX)

**REPLY IN SUPPORT OF
SIEMENS' MOTION FOR
PARTIAL SUMMARY
JUDGMENT OF INVALIDITY
BASED ON INDEFINITENESS
OF "CONSPICUITY" IN CLAIMS
1, 3-7, 11-13, 18-20, 22-25, 28, & 35
IN U.S. PATENT NO. 5,560,360**

**The Hon. Mariana R. Pfaelzer
United States District Court Judge**

**Hearing Date: October 5, 2011
Time: 11 a.m.
Location: Courtroom 12**

1
2 SIEMENS MEDICAL SOLUTIONS USA,
3 INC.

4 Counterclaim Plaintiff,

5 vs.

6 NEUROGRAFIX, and WASHINGTON
7 RESEARCH FOUNDATION,

Counterclaim Defendants.
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EXHIBIT LIST

The following exhibits are to the Declaration of Sean M. McEldowney, filed concurrently. References to the File History for U.S. Patent No. 5,560,360 are cited as “JA__” and refer to the parties Joint Appendix submitted on February 11, 2011 (D.I. 102).

Exhibit IND 18: Excerpts from the deposition of Michael N. Brant-Zawadzki, M.D., dated August 16, 2011

Exhibit IND19: Excerpts from the deposition of R. Nick Bryan, M.D., dated September 7, 2011

Exhibit IND20: Declaration of R. Nick Bryan, M.D., dated September 22, 2011

Exhibit IND21: Excerpts from the deposition of Jay Tsuruda, M.D., dated February 25, 2011

Exhibit IND22: Excerpts from the rebuttal expert report of Aaron G. Filler, M.D., dated February 1, 2011

Exhibit IND23: L. C. Blake et al., *Sacral Plexus: Optimal Imaging Planes for MR Assessment*, 199(3) *Radiology* 767 (1996); TSURUDA001636-41

Exhibit IND24: Excerpts from the deposition of Aaron G. Filler, M.D., dated February 22, 2011

1 The testimony and expert analyses from Plaintiffs' first expert (Dr. Filler),
2 Plaintiffs' second expert (Dr. Brant-Zawadzki), and Siemens' experts (Dr. Bryan and
3 Dr. Moseley) all show that the '360 patent does not tell users how they should select
4 ROIs, and there is no agreed standard in the medical imaging field for selecting ROIs.
5 (Br. at 7-11.) The analyses by those experts (as well as all of the literature in the field)
6 also show that different ROI selection methods lead to different ROIs, and that even
7 slightly different ROIs lead to substantially different conspicuity measurements. (Br.
8 at 11-17.) "Conspicuity" is indefinite and this Court should so find.

9 Plaintiffs' opposition brief simply ignores all that and instead tries to start over
10 with a new expert declaration from Dr. Filler showing ROI selection methods that are
11 not disclosed in the patent and that were never previously described in the six expert
12 reports addressing ROI selection. Even if it is not excluded as untimely, the Court
13 should nevertheless disregard Dr. Filler's proposal because it is flatly contrary to all of
14 the other evidence in this case, including Dr. Filler's prior opinions in this case.
15 Finally, Dr. Filler's new declaration creates no genuine dispute of material fact even if
16 it is accepted as true.

17 **I. Plaintiffs' Opposition Does Not Address, Let Alone Raise Any Genuine**
18 **Dispute, About the Material Facts that Render the Conspicuity Term**
19 **Indefinite.**

20 Siemens' opening brief argued that "conspicuity" is indefinite based on four
21 points. (Br. at 5 (summarizing argument).) Plaintiffs' opposition brief effectively
22 concedes the first and second and responds to the third and fourth with the incredible
23 suggestion that the Court should ignore all of the prior evidence in this case and
24 instead simply accept Dr. Filler's new declaration combined with factually
25 unsupported attorney argument.

26 **A. The Patent Does Not Tell Users the Way They Should Select ROIs.**

27 The patent refers to many different ways of selecting ROIs, but it never says
28 that one of them is *the* way to select ROIs. Siemens' expert, Dr. Bryan, and

1 Plaintiffs' expert, Dr. Brant-Zawadzki, both concluded that a person of skill in the art
2 would find nothing in the patent telling them which of the many possible ROI
3 selection methods to use for conspicuity measurements. (Siemens' Br. at 7-8 (quoting
4 IND2 at ¶35 and IND1 at 108:18-22; 109:2-10.) Rather, the choice of how to draw an
5 ROI is left to the subjective choice of the operator. (IND1 at 109:2-10 (Plaintiffs'
6 expert agreeing the '360 patent "leaves that choice up to the operator").)

7 Dr. Filler's new declaration proposes two new ways to select ROIs, specifically,
8 what Plaintiffs refer to as a "thresholding process" for nerve ROIs and a "two
9 centimeter" region for non-neural tissue. But Plaintiffs make a fatal concession—they
10 continue to acknowledge that the '360 patent also permits other ways for choosing
11 ROIs. For instance, Plaintiffs say that in addition to their proposed "thresholding
12 process," the nerve ROI could also be selected using "built-in tools to select the tissue
13 known to be nerve and not artifact," or, "as another example," "representative regions
14 of interest could also be used when the signal intensity of the identified nerve is
15 relatively homogenous."¹ (Pls'. Br. at 10.) Plaintiffs also concede that multiple
16 methods can be used for selecting ROIs in non-neural tissue. (*Id.* at 12.)

17 Of course, the existence of these other ways is fatal to Plaintiffs' argument,
18 because the claims are indefinite if the patent teaches multiple ways of drawing ROIs
19 that can lead to different conspicuity measurements—which is exactly the case here.²
20 (*See infra* section I(C).) *See Honeywell Int'l, Inc. v. Int'l Trade Comm'n*, 341 F.3d

21
22 ¹ As Dr. Bryan explained, Plaintiffs' contention that there are tissues with
23 homogeneous signal intensities in an MR image is wrong. (Ex. IND19, Bryan Tr. at
24 44:21-49:21.)

25 ² Citing *Hybritech*, Plaintiffs assert, without citing any factual support, that "the '360
26 patent indicates a precise as possible method for selecting the appropriate ROI within
27 the nerve" and that "the selection of regions of interest of non-neural tissue is
28 described as specifically as the science will allow." (Pls'. Br. at 10, 11.) But
Plaintiffs' own expert unequivocally explained that the '360 patent does not even
provide the level of detail for ROI selection that would be provided in a medical
journal article, even though it could have done so. (Siemens' Br. at 10-11.)

1 1332, 1341 (Fed. Cir. 2003) (claim indefinite because patent did not dictate the single
2 way of preparing samples to determine the claimed melting point elevation and “the
3 different sample preparation methods do not produce identical or even ‘essentially
4 identical results’”); *see also Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d
5 1313, 1341-43 (Fed. Cir. 2003); *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 2008 WL
6 4083145, at *8-9 (N.D. Ill. 2008).

7 **B. There Is No Agreed Standard that Persons of Skill in the Art Use for**
8 **Selecting ROIs.**

9 Everyone agrees that there is no industry standard for selecting ROIs.
10 (Siemens’ Br. at 8-11.) Although Plaintiffs do not appear to dispute that fact (D.I. 152
11 at 4, SUF 4, 9), Plaintiffs do argue that it is not material. (*Id.*) But whether there is an
12 agreed standard for selecting an ROI is the *critical* question the Court found
13 unanswered regarding conspicuity. The basis for the unresolved issue the Court
14 pointed to in its claim construction order was Plaintiffs’ assertion that “selecting [a
15 region of interest] representative of [tissue] is a *standard task in the field* of
16 medicine.” (D.I. 114 at 15.) This fact is material for good reason—without either an
17 industry standard or any disclosure in the ‘360 patent showing the one single way to
18 select ROIs, a person of skill is left with no objective basis for choosing one way over
19 another. *Amgen Inc.*, 314 F.3d at 1341-43 (finding claims indefinite because multiple
20 industry standards existed in the art to detect the claimed glycosylation and patent
21 specification failed to disclose the appropriate industry standard); *Baldwin Graphic*,
22 2008 WL 4083145, at *8–9.

23 **C. The Scope of the Conspicuity Term Depends on Who Selects the**
24 **ROIs and How They Select the ROIs.**

25 Based on sample ROI measurements, Dr. Bryan, Dr. Filler, Dr. Moseley, and all
26 of the literature in the field demonstrate that even slight differences in ROI selections
27 can lead to substantial differences in signal intensity measurements. (Siemens’ Br. at
28 11-14.) That same evidence also confirms that, as a result of this ROI variability, an

1 infringement determination depends on who draws the ROIs and precisely how they
2 are drawn. (Siemens' Br. at 14-17 (demonstrating that Dr. Filler's analysis leads to
3 different conclusions about whether an image shows the required conspicuity,
4 depending on how he draws his ROIs); *see also* Ex. IND21, Tsuruda Tr. at 91:20-23
5 (Q. "Does the region [of interest] selected to measure that intensity make a difference
6 if you are trying to do some quantitative conspicuity measure?" A. "Yes.").)

7 Plaintiffs respond in two ways. **First**, they make unsupported assertions that
8 their ROI selection proposals lead to repeatable conspicuity measurements. (Pls'. Br.
9 at 2 (asserting, without support, that the "thresholding process" is "definite and
10 repeatable"); *id.* at 8 (asserting, without support, that "the calculation of conspicuity is
11 both reproducible and repeatable"); *id.* at 10 (asserting, without support, that the
12 different ROI methods are "equivalent"); *id.* at 11 (asserting, citing "*supra*" without a
13 pinpoint cite, that the patent shows a "repeatable method for selecting the appropriate
14 non-neural tissue"); *id.* at 16 (asserting, without support, that "the '360 patent teaches
15 a person of ordinary skill in the art a definite and repeatable method for calculating
16 conspicuity").³ Plaintiffs cannot overcome Siemens' evidentiary showing with mere
17 attorney argument. *British Airways Bd. v. Boeing Co.*, 585 F.2d 946, 952 (9th Cir.
18 1978); *Estrella v. Brandt*, 682 F.2d 814, 819-20 (9th Cir. 1982); *Invitrogen Corp. v.*
19 *Clontech Labs., Inc.*, 429 F.3d 1052, 1068-69 (Fed. Cir. 2005).

20
21 ³ Plaintiffs also assert that "the result [of Dr. Filler's newly proposed thresholding
22 process] will be a consistent region of interest for the nerve." (Pls'. Br. at 10.)
23 Although they cite ¶7 of Dr. Filler's declaration and ¶21 from Dr. Brant-Zawadzki's
24 rebuttal report, neither of those paragraphs opines, let alone demonstrates, that Dr.
25 Filler's "thresholding process" leads to a consistent ROI. And although Plaintiffs cite
26 Dr. Bryan to support their assertion that "the signal intensity will not change
27 meaningfully if different sizes and shapes of selected regions of interest are used," that
28 citation misrepresents Dr. Bryan's testimony. (Pls'. Br. at 10 n.10.) Dr. Bryan was
responding to a question that was based on two assumptions that Dr. Bryan testified
could never exist. (Ex. IND19, Bryan Tr. at 49:6-8 ("[I]t is a very hypothetical
question, because such conditions really never exist in practice...."); *see also id.*
44:21-49:21; Ex. IND2, Bryan Opening Report, ¶¶41, 46-53.)

1 **Second**, Plaintiffs argue that the ROI measurements submitted by Dr. Bryan
2 and Dr. Filler (which demonstrate that ROI selection substantially affects conspicuity
3 measurements) were not done according to the teachings of the '360 patent. (Pls'. Br.
4 at 15.) That argument discredits the very evidence (i.e., Dr. Filler's report) that
5 Plaintiffs relied on during claim construction to avoid a finding that the claims are
6 indefinite. It also ignores all of the other evidence in this case. For instance, Dr.
7 Brant-Zawadzki (who is, unlike Dr. Filler, a radiologist and an independent expert)
8 explained that, based on the disclosure in the '360 patent, persons of skill in the art
9 would use the methods that Dr. Bryan and Dr. Filler (in February 2011) used in their
10 expert reports:

11 Q. What is your understanding of the patent's discussion of several
12 different methods of selecting ROIs?

13 A. [T]he patent teaches use of common, very common region of
14 interest tools, an oval or a circle being **shown by Dr. Filler and Dr.**
 Bryan commonly in the exhibits [to their expert reports].

15 (Ex. IND18, Brant-Zawadzki Tr. at 218:8-23; *see also* Ex. IND1, Brant-Zawadzki Tr.
16 at 126:21-127:7 ("Most people would do it the way [Dr. Bryan] did it."); *id.* at
17 177:13-20 (testifying that the way Dr. Filler selected ROIs in his February 2011 report
18 is one of the ways taught by the patent); *id.* at 25:5-20 ("I think [Dr. Bryan]
19 demonstrated how a radiologist...creates a region of interest").)

20 And in a discussion that spans 24 pages of deposition transcript, Dr. Brant-
21 Zawadzki identified several of Dr. Bryan's ROIs that he believes **are consistent** with
22 the teachings in the '360 patent. (Ex. IND18, Brant-Zawadzki Tr. at 189:18-213:23.)
23 For instance:

24 Q. You agree that the nerve ROIs [in figure 3 of Dr. Bryan's report,
25 which shows nerve ROI Nos. 8 and 10,] are all ones that someone
 with skill in the art could choose **based on the teachings of 360**?

26 A. [I] would say that they could possibly choose 10. I would say most
27 of the time they would choose 8.

28 * * *

1 Q. Are those nerve ROIs [in figure 7 of Dr. Bryan's report], in your
2 view, **consistent with the teachings of the 360 patent**?

3 A. [T]he upper ROI is consistent, and the two on the left are
4 consistent. I would choose the upper one more than the lower one,
5 but **they're consistent with it, yes**.

6 (Ex. IND18, Brant-Zawadzki Tr. at 199:6-13; Ex. IND1 at 208:16-24; *see also* D.I.
7 144-10, Brant-Zawadzki Rebuttal Report ¶34 (stating that the ROIs in figure 5 of Dr.
8 Bryan's Exhibit C are "consistent with the adjacent non-neural tissue limitation of
9 claim 18").)⁴

10 Tellingly, in those 24 pages of testimony, Dr. Brant-Zawadzki **never once** said
11 that Dr. Bryan's or Dr. Filler's ROIs were inconsistent with the '360 patent because
12 they failed to use Dr. Filler's newly proposed "thresholding process" or Dr. Filler's
13 newly proposed "two centimeter" method.⁵ Rather, Dr. Brant-Zawadzki's only
14 objection to most of these ROI selections was that he would move the particular ROI a
15 "little bit further down" or "a smidgen further down the nerve on the left." (Ex.
16 IND18, Brant-Zawadzki Tr. at 209:6-16, Ex. IND1 at 199:18-200:3.) That is how one
17 of skill in the art would select ROIs based on the '360 patent, and that is a purely
18 subjective method. *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1350
19 (Fed. Cir. 2005).

20 ⁴ The conspicuity term is indefinite regardless of whether the non-neural ROI is
21 "adjacent" (as claim 18 requires) or not (claims 1-17). (*See, e.g.*, Ex. IND2, Bryan
22 Opening Rep. ¶¶57-58, Ex. IND12, Ex. C to Bryan Rep. Figs. 5 & 6.) Indeed, Dr.
23 Brant-Zawadzki concedes the Dr. Bryan correctly selected "adjacent" non-neural
24 tissue in his Figure 5, which resulted in conspicuity of less than 1.1. (D.I. 144-10,
25 Brant-Zawadzki Rebuttal Report ¶34.) The fact that Dr. Brant-Zawadzki is uncertain
26 "what structures Dr. Bryan is selecting" in Figure 5 (*id.*) only highlights that those of
27 ordinary skill in the art cannot even accurately and objectively identify a nerve in the
28 images purportedly created by the '360 patent, much less agree on whether a nerve
meets the "conspicuity" limitation.

⁵ Dr. Tsuruda, one of the named inventors on the patent, also did not suggest Dr.
Filler's newly proposed methods for calculating conspicuity. (Ex. IND21, Tsuruda
Tr. at 180:24-181:8, 14-15.)

1 All of the *evidence* shows that ROI selection substantially affects signal
2 intensity measurements and therefore conspicuity measurements. (Siemens' Br. at 11-
3 17.) Dr. Brant-Zawadzki did not submit any ROI selections or conspicuity
4 measurements rebutting any of that evidence. (*Id.* at 13.) And although Dr. Filler's
5 new declaration demonstrates that Dr. Filler is able to concoct new ways to draw
6 ROIs, he does not assert nor show that those methods could be reproduced by another
7 operator, or even by Dr. Filler himself. (*But see id.* at 12, 15-16 (showing that when
8 Dr. Filler measures the signal intensity and conspicuity of the same structures in the
9 same images twice, he reaches different conclusions).)

10 **II. The '360 Patent Does Not Disclose Dr. Filler's Newly Proposed**
11 **"Thresholding Process" as the Way of Selecting Nerve ROIs.**

12 Contrary to Plaintiffs' argument, the patent does not suggest using a
13 "thresholding process" to select nerve ROIs, much less using the so-called
14 "thresholding process" shown in Dr. Filler's new declaration. And Dr. Filler's new
15 declaration merely highlights the inadequacy of the disclosure in the patent.

16 *First*, to support Dr. Filler's newly proposed ROI selections, Plaintiffs rely on a
17 few references in the patent to "thresholding process." (Pls'. at 8-9.) But those
18 references do not suggest using a thresholding process to select ROIs for conspicuity
19 measurements. Rather, the '360 patent says "thresholding" could be used to help find
20 "regions of the image *potentially* representative of nerve." ('360 patent, 28:2-4; *see*
21 *also id.* at 21:55-57 (thresholding can be used to help "detect" "the location of
22 nerves").) That does not suggest using thresholding to draw the actual ROIs once a
23 nerve has been found. To the contrary, the "thresholding" discussion in columns 27
24 and 28 is describing thresholding to identify bright spots in an image that can then be
25 analyzed for a "fascicular pattern" to help determine whether the bright spot is a
26 nerve. ('360 patent, 28:8-16; *see also id.* at 28:17-19.) This fascicle identification
27 method is expressly disclosed as an *alternative* to relying on conspicuity, not a way of
28 measuring conspicuity. ('360 patent, 27:57-60 (fascicles analysis used to identify

1 nerves “when the conspicuity or signal intensity of a particular nerve does not permit
2 identification”).)

3 Before he manufactured his new expert declaration opining that thresholding is
4 the way to draw ROIs for conspicuity measurements, Dr. Filler confirmed precisely
5 this understanding of the patent. He testified that the thresholding process described
6 at column 28, lines 2 through 7 in the patent is a method of “doing the fascicle
7 identification,” and that the inventors made clear in the patent that “we’re not going to
8 call that conspicuity.”⁶ (Ex. IND 24, Filler Tr. at 122:2-11, 2-25, 123:23-124:2; *see*
9 *also id.* at 124:3-6 (Q. “And you believe this language in the patent tells the
10 reader...*do not use [the thresholding discussion at 28:2-7] in calculating*
11 *conspicuity.*” A. “*Right.*”); *id.* at 134:16:20 (the ‘360 patent “talk[s] about the
12 fascicle identification as an *alternate* to conspicuity”).)

13 *Second*, the “thresholding process” described in the patent does not even work
14 for identifying nerves, let alone for identifying precise ROIs within nerves. (Ex.
15 IND19, Bryan Tr. at 73:8-76:13 (“[C]ould I use the thresholding method to select
16 those bright areas as nerves. And the answer to that question is no.”).) Using this
17 method to identify nerves, as Plaintiffs now suggest, would require the nerves to be
18 the brightest structures in the image. But Dr. Bryan demonstrated that there was no
19 nerve tissue within the brightest 50% of the pixels in the images Plaintiffs contend
20 were made using the patented method. (Ex. IND3, Bryan Rebuttal ¶24; Ex. IND17,
21 Bryan Rebuttal Ex. 2, fig.5.) And when the threshold is lowered to include the
22 brightest 70% of the pixels in the image, a level where nerves are finally seen, there is
23 a significant amount of non-neural tissue highlighted as well, such that thresholding

24
25 ⁶ Dr. Filler never raised his newly proposed “two centimeter” or “thresholding”
26 methods during his deposition or in his expert report last winter, which is a sufficient
27 reason by itself to reject Dr. Filler’s new declaration— “a party cannot create an issue
28 of fact by an affidavit contradicting his prior deposition testimony.” *Kennedy v. Allied*
Mut. Ins. Co., 952 F.2d 262, 266 (9th Cir. 1991); *see also Cleveland v. Policy Mgmt.*
Sys. Corp., 526 U.S. 795, 806–07 (1999) (collecting cases).

1 alone does not distinguish neural from non-neural tissue. (Ex. IND3, Bryan Rebuttal
2 ¶24; Ex. IND17, Bryan Rebuttal Ex. 2, fig.7.; *see also* Ex. IND18, Brant-Zawadzki
3 Tr. at 214:10-13, 215:12-216:10 (agreeing with Dr. Bryan's analysis).)

4 Even if an operator tried to use some kind of thresholding method to select
5 ROIs, he or she would have to fill in many critical gaps left open by the disclosure in
6 the patent. As Dr. Bryan explained:

7 [A]s stated here, *the thresholding process is so vague as to be*
8 *useless...*[T]his phrase does not help me set up an ROI at all....[I]f this is
9 to be taken as an attempt at an operational definition of a thresholding
10 process to establish an ROI, *it is of no practical use, it does not*
sufficiently guide anyone to make an ROI. It is too vague.”.)

11 (Ex. 19, Bryan Tr. at 72:6-73:6; *see also* Ex. IND18, Brant-Zawadzki Tr. at 63:9-12
12 (“[The patent] doesn’t specify automated thresholding versus manual versus oval
13 window versus -- but it says thresholding.”).)

14 *Third*, the method Dr. Filler describes in his new expert declaration is not
15 described in the ‘360 patent, nor is it simply “thresholding.”⁷ Rather, the method Dr.
16 Filler uses in his new exhibits appears to use a type of segmentation algorithm referred
17 to as a region-growing algorithm. (Ex. IND20, Bryan 9/22/2011 Decl. ¶10a.)⁸
18 Contrary to Dr. Filler’s new analysis, Dr. Brant-Zawadzki opined that “segmentation

19 ⁷ A person of skill in the art would understand “thresholding” to refer to highlighting
20 all of the pixels in an image that fall above a certain brightness value. (Ex. IND18,
21 Brant-Zawadzki Tr. at 40:19-41:9; *see also* Ex. IND19, Dr. Bryan Tr. at 77:9-16 (one
example of “thresholding” is a “process to identify the brightest” area in an image).)

22 ⁸ For the reasons explained in the concurrently-filed motion to strike (D.I. 157),
23 Siemens contends Dr. Filler’s untimely declaration and exhibits should be stricken.
24 Siemens had ten days to review Dr. Filler’s new analysis before filing this reply brief.
25 Siemens’ expert, Dr. Bryan, had even less time. Indeed Plaintiffs did not provide all
26 of the MRI-format files for Dr. Filler’s analysis until several days after filing Dr.
27 Filler’s images. Despite the limited time, and based on the incomplete explanation
28 Plaintiffs provided regarding how Dr. Filler actually drew his new ROIs, (IND20,
Bryan 9/22/2011 Decl., ¶3, p.6 n.2, p.7 n.3), Dr. Bryan identified several fundamental
problems with Dr. Filler’s new analysis, which Dr. Bryan points out in his attached
declaration.

1 algorithms [are] irrelevant” to selecting ROIs for measuring conspicuity in the ‘360
2 patent. (Ex. IND3, Brant-Zawadzki Rebuttal Report, ¶26.) Yet that is precisely what
3 Dr. Filler is now proposing.

4 Further, Dr. Filler’s Exhibit 20 indicates that he had to make up several aspects
5 of his ROI selection method. (Ex. 20 to Filler Decl. (selecting the algorithm, the
6 intensity interval, “brush ROI” rather than “polygon,” and the relative number of
7 pixels to include); *see also* Ex. IND20, Bryan 9/22/2011 Decl. ¶10b.) None of those
8 options is disclosed in the patent, nor does the patent even disclose using a region-
9 growing algorithm at all. *S.O.I.TEC Silicon On Insulator Techs., S.A. v. MEMC Elec.*
10 *Materials, Inc.*, 745 F. Supp. 2d 489, 508-09 (D. Del. 2010) (finding claims indefinite
11 because expert’s proposed “technique does not appear in the...patent, and cannot be
12 used to satisfy § 112, [¶2]”).⁹

13 Dr. Filler’s new analysis therefore merely highlights that the “thresholding
14 process,” as it is actually described in the ‘360 patent, cannot be used to select ROIs
15 unless the operator makes many subjective leaps of judgment to fill the gaps left by
16 the disclosure in the patent. *Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys.*,
17 132 F.3d 701, 706 (Fed. Cir. 1997) (finding inventor’s testimony “concerning claim
18 construction is...entitled to little or no deference [because it] often is a self-serving,
19 after-the-fact attempt to state what should have been part of his or her patent
20 application”); *Howmedica Osteonics Corp. v. Wright Med. Tech., Inc.*, 540 F.3d 1337,
21 1346 (Fed. Cir. 2008) (“The testimony of an inventor cannot be relied on to change
22 the meaning of the claims.”).

23
24
25 ⁹ Plaintiffs point to column 30 as purported support for Dr. Filler’s newly proposed
26 region-growing method. That section merely says that “the system 24...determines
27 the boundaries of the imaged nerve” and that it will be “readily able” to do so. But
28 there are many different ways a person of skill in the art could try to determine the
boundaries of a nerve, each leading to a different result. (Ex. IND2, Bryan Opening
Report, ¶40.)

1 **III. The ‘360 Patent Does Not Disclose Dr. Filler’s Newly Proposed “Two**
2 **Centimeter” Method as the Way of Selecting Non-Neural ROIs.**

3 Also contrary to Plaintiffs’ argument, the patent does not “teach” drawing non-
4 neural ROIs to include “all of the *non-neural* tissue from approximately 2 centimeters
5 around the nerve.” (Pls.’ Br. at 12 (citing ‘360 patent, 27:29-35).) And, again, Dr.
6 Filler’s new declaration highlights the inadequacy of the disclosure in the patent.

7 *First*, the passage of the patent that Plaintiffs rely on for this new proposal
8 (‘360 patent, 27:29-43) is a passage that has nothing to do with drawing an ROI in
9 *non-neural* tissue, nor measuring conspicuity. To the contrary, this passage in the
10 patent is proposing to capture just the sciatic *nerve* in order to process the nerve
11 region of the image to generate other images “*of the sciatic nerve.*” (‘360 patent,
12 27:36-43; *see also* Ex. IND20, Bryan 9/22/11 Decl., ¶¶7, 8a-c.) Consistent with
13 selecting only nerve tissue, the patent explains that this two centimeter region “was
14 selected *to exclude*” *non-neural tissue* such as “blood vessels.” (‘360 patent, 27:32-
15 33; *see also id.* claims 15 and 30 (requiring “the non-neural tissue” includes “blood
16 vessels”).) Indeed, the diameter of the cross-section of a sciatic nerve is
17 approximately two centimeters, and therefore a two centimeter ROI “around the
18 sciatic nerve” would encompass little, if any, non-neural tissue. (Ex. IND23; Ex.
19 IND20, Bryan 9/22/2011 Decl., ¶8b.) It is therefore not surprising that in six expert
20 reports and four expert depositions, none of the experts ever raised this two centimeter
21 ROI disclosure as a potential description of a non-neural ROI (nor, for that matter, a
22 neural ROI¹⁰) for conspicuity measurements. (Ex. IND1, Brant-Zawadzki Tr. at
23 56:19-23 (Q. “[D]oes the patent describe a particular size or shape region of interest to
24 use?” A. “No.”).)

25 ¹⁰ Plaintiffs have not, nor could they plausibly, contend that this two centimeter region
26 should be used for selecting ROIs in nerves. Although the sciatic nerve is
27 approximately two centimeters in cross-section, other peripheral nerves are much
28 smaller. (Ex. IND2, Bryan Opening Report, ¶¶ 37, 43; Ex. IND23.) Further, this
disclosure says nothing about the placement of the ROI on the nerve.

1 **Second**, the only support for this newly proposed ROI selection method is
2 therefore Plaintiffs' counsel's argument based on Dr. Filler's late expert declaration.¹¹
3 But what Dr. Filler did in his Exhibits, in fact, is not even what Plaintiffs describe in
4 their brief. (Ex. IND20, Dr. Bryan 9/22/2011 Decl., ¶¶ 9b-c.) While Plaintiffs' brief
5 suggests that Dr. Filler's simply drew a two centimeter ROI, that is just one step in Dr.
6 Filler's proposed non-neural ROI method. Dr. Filler appears to have also used a
7 segmentation algorithm to identify a portion of nerve,¹² and then subtracted that
8 portion of the nerve to get an annular region around that portion of the nerve. (Exs.
9 15, 16 to Filler Decl.; Ex. IND20, Bryan 9/22/2011 Decl., ¶¶ 9d-e.) And Dr. Filler also
10 appears to have manually modified his ROI to exclude portions from his two
11 centimeter circle. (*Id.* (showing irregular cutout shapes from red region of interest.)
12 Dr. Filler has not disclosed the basis for excluding those portions, nor how he
13 excluded them, and the patent provides no basis or method for doing so.¹³ (Ex.
14 IND20, Dr. Bryan 9/22/2011 Decl., ¶¶ 9b.); *S.O.I.TEC Silicon On Insulator Techs.*,
15 *S.A.*, 745 F. Supp. 2d at 508-09 .

16 Dr. Filler's newly proposed non-neural ROI is hinges on his own subjective
17 opinion in an eleventh hour submission designed to generate the appearance of an
18 issue of disputed fact where none exists. *See, e.g., Roton Barrier, Inc. v. Stanley*

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20
21 ¹¹ Plaintiffs suggest that their newly proposed method is consistent with an article by
22 Hallberg. (Pls.' Br. at 13 & n.12.) But Dr. Filler previously asserted that "Dr.
23 Moseley's citation to the conspicuity algorithms" in the same Hallberg article "is
24 ***inappropriate and misleading***" because Hallberg involved X-ray, not MRI. (Ex.
25 IND22, Filler Rebuttal ¶44.) In any event, the disclosure in the '360 patent controls,
26 and it does not disclose using a two centimeter region for selecting a non-neural ROI.

27 ¹² In fact, it appears Dr. Filler may have used different segmentation algorithms to
28 select the nerve in his Exhibits 15, 16, and 20. (Ex. IND20, Bryan 9/22/2011 Decl., at
7 n.3.)

¹³ Notably, Dr. Filler's purported non-neural ROIs in his Exhibit 15 likely include
neural tissue as well. (Ex. IND20, Dr. Bryan 9/22/2011 Decl., ¶¶ 9a-b.)

1 *Works*, 79 F.3d 1112, 1126 (Fed. Cir. 1996) (“an inventor’s after-the-fact testimony is
2 of little weight compared to the clear import of the patent disclosure itself”).

3 **IV. Conclusion**

4 For these reasons, Siemens respectfully requests the Court grant summary
5 judgment of invalidity dismissing claims 1, 3-7, 11-13, 18-20, 22-25, 28, & 35 as
6 indefinite.

7
8 Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 22, 2011, a copy of the foregoing REPLY IN SUPPORT OF SIEMENS' MOTION FOR PARTIAL SUMMARY JUDGMENT OF INVALIDITY BASED ON INDEFINITENESS OF "CONSPICUITY" IN CLAIMS 1, 3-7, 11-13, 18-20, 22-25, 28, & 35 IN U.S. PATENT NO. 5,560,360 was served upon counsel of record for Plaintiffs registered with the Court's CM/ECF system.

/s/Sean M. McEldowney